ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA–HQ–OPPT–2016–0654; FRL–9957–75]

RIN 2070–AK20

Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: As required under section 6(b)(4) of the Toxic Substances Control Act (TSCA), EPA is proposing to establish a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. Risk evaluation is the second step, after Prioritization, in a new process of existing chemical substance review and management established under recent amendments to TSCA. This proposed rule identifies the steps of a risk evaluation process including scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination. EPA is proposing that this process be used for the first ten chemical substances to be evaluated from the 2014 update of the TSCA Work Plan for Chemical Assessments, chemical substances designated as High-Priority Substances during the prioritization process, and those chemical substances for which EPA has initiated a risk evaluation in response to manufacturer requests. The proposed rule also includes the required ''form and criteria'' applicable to such manufacturer requests.

DATES: Comments must be received on or before March 20, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0654, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Susanna W. Blair, Immediate Office, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–4371; email address: *blair.susanna@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

EPA is primarily proposing to establish requirements on the Agency. However this proposal also includes the process and requirements that manufacturers (including importers) would be required to follow when they request an Agency-conducted risk evaluation on a particular chemical substance. This action may, therefore, be of interest to entities that are manufacturing or importing, or may manufacture or import a chemical substance regulated under TSCA (*e.g.,* entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What action is the agency taking?

EPA is proposing to establish the process by which the Agency would conduct risk evaluations on chemical substances under TSCA. The proposal identifies the necessary components of a risk evaluation, including a scope (composed of a conceptual model and an analysis plan), a hazard assessment, an exposure assessment, a risk characterization, and a risk determination. The proposed rule would also establish the process by which manufacturers (including importers) would request an Agency-conducted risk evaluation, and the criteria by which the EPA would evaluate such requests.

C. What is the agency's authority for taking this action?

EPA is proposing this rule pursuant to the authority in TSCA section 6(b)(4), as amended (15 U.S.C. 2605(b)). See also the discussion in Units II.A. and B.

D. What are the estimated incremental impacts of this action?

Although this proposal focuses on the process and activities that apply to EPA, it also proposes the process and requirements that manufacturers (including importers) would be required to follow when they request an Agency-conducted risk evaluation on a particular chemical substance. Since these requirements qualify as an information collection under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* EPA has prepared an Information Collection Request (ICR) to estimate the potential burden and costs associated with the proposed requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. The ICR, which is available in the docket, is discussed in Unit VI.B. and is briefly summarized here. (Ref. 1).

The total estimated annual burden is 960.3 hours and $69,353, which is based on an estimated per request burden of 96.03 hours.

E. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets*.

II. Background

A. Recent Amendments to TSCA

On June 22, 2016, the President signed into law the ''Frank R. Lautenberg Chemical Safety for the 21st Century Act,'' which imposed sweeping reforms to TSCA. The bill received broad bipartisan support in the U.S. House of Representatives and Senate, and its passage was heralded as the most significant update to an environmental law in over 20 years. The amendments give EPA improved authority to take actions to protect people and the environment from the effects of dangerous chemical substances. Additional information on the new law is available on EPA's Web site at: *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act.*

When TSCA was originally enacted in 1976, it established an EPA-administered health and safety review process for new chemical substances prior to allowing their entry into the marketplace. However, tens of thousands of chemical substances in existence at that time were ''grandfathered in'' with no requirement for EPA to ever evaluate their risks to health or the environment. The absence of a review requirement or deadlines for action, coupled with a burdensome statutory standard for taking risk management action on existing chemical substances, resulted in very few chemical substances ever being assessed for safety by EPA, and even fewer subject to restrictions to address identified risks.

One of the key features of the new law is the requirement that EPA now systematically prioritize and assess existing chemicals, and manage identified risks. Through a combination of new authorities, a risk-based safety standard, deadlines for action, and minimum throughput requirements, TSCA effectively creates a ''pipeline'' by which EPA will conduct existing chemicals review and management. This new pipeline—from prioritization to risk evaluation to risk management (when warranted)—is intended to drive steady forward progress on the backlog of existing chemical substances left largely unaddressed by the original law. Risk evaluation is the second step of this process, after prioritization, which is being addressed in a separate rulemaking.

B. Statutory Requirements for Risk Evaluation

TSCA section 6(b)(4) requires EPA to establish, by rule, a process to conduct risk evaluations. Specifically, EPA is directed to use this process to ''determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.'' (15 U.S.C. 2605(b)(4)(A)). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances must undergo evaluation, the development of criteria for manufacturer-requested evaluations, the minimum components of an Agency risk evaluation, and the timelines for public comment and ultimate completion of the risk evaluation.

1. Chemical substances to undergo risk evaluation. TSCA section 6(b) identifies the chemical substances that are subject to this process; these are: (1) Ten chemical substances the Agency is required to identify from the 2014 update to the TSCA Work Plan within the first 180 calendar days after the signing of TSCA (15 U.S.C. 2605(b)(2)); (2) the chemical substances determined as High-Priority Substances through the prioritization process that is being proposed in a separate rulemaking; and (3) requested chemicals submitted by manufacturers that have met the criteria for EPA to conduct a risk evaluation as outlined by this rule. Assuming a sufficient number of requests that have met the criteria outlined in this proposed rule are received, subsection (E) specifies that the number of manufacturer-requested evaluations be 25 to 50 percent of the number of ''High Priority'' risk evaluations ongoing at any one time. Since the number of manufacturer-requested evaluations is expressed as a percentage of the number of High-Priority Substance evaluations, not as a percentage of the total, the number of manufacturer-requested evaluations will likely comprise between 1/5 and 1/3 of the number of total ongoing evaluations, assuming a sufficient number of compliant requests are received. Any manufacturer requested chemical substances on the 2014 update of the TSCA Work Plan (Ref. 2) are exempt from the percentage limitations.

2. Manufacturer-requested risk evaluations. TSCA section 6(b)(4)(C) directs EPA to establish the ''form and manner'' and ''criteria'' that govern manufacturer requests that a substance that they manufacture undergo an EPA conducted risk evaluation. EPA has broad discretion to establish these criteria, but relatively less discretion over whether to grant requests that comply with EPA's criteria. EPA must grant any request that complies with EPA's criteria, until the statutory minimum of 25 percent has been met. Assuming EPA receives requests in excess of this threshold, EPA interprets this provision to grant EPA discretion to determine whether to grant further requests, up to the maximum 50 percent level. In such circumstances, the EPA is directed to give preference to manufacturer requests for which the EPA determines that restrictions imposed by one or more states have the potential to significantly impact interstate commerce, or health or the environment. 15 U.S.C. 2605(b)(4)(E)(iii). As discussed elsewhere in this preamble, EPA is also proposing to give preference to requests where EPA estimates there may be relatively high exposure(s) and/or hazard(s) under one or more conditions of use.

3. Components of a risk evaluation. The statute identifies the minimum components EPA must include in all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation that will be conducted, and that includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the EPA expects to consider. 15 U.S.C 2605(b)(4)(D). The statute provides that the scope of the risk evaluation must be published no later than six months after the initiation of the risk evaluation.

Each risk evaluation must also: (1) ''integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations;'' (2) ''describe whether aggregate or sentinel exposures were considered and the basis for that consideration;'' (3) ''take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use;'' (4) ''describe the weight of scientific evidence for the identified hazards and exposure.'' 15 U.S.C. 2605(b)(4)(F)(i),(iii)–(v). The risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(ii).

Many stakeholders have expressed concern as to how EPA will apply ''weight of scientific evidence'' under

the amended TSCA. EPA is providing, for the purposes of background, a description of how the Agency has consistently interpreted and applied that concept. EPA is not proposing to modify this process as part of this rule. Nor is EPA proposing to codify it; this process has and will continue to evolve with changing scientific methods and innovation. Codifying a specific definition can inhibit the flexibility of the Agency to quickly adopt and implement changing science.

The phrase weight-of-evidence (WoE) is used by EPA and other scientific bodies to describe the strength of the scientific inferences that can be drawn from a given body of evidence, specifically referring to how studies are selected, the quality of the studies evaluated, and how findings are assessed and integrated. Weight-of-evidence is a complex issue and as stated by the National Academies this is ''because scientific evidence used in WOE evaluations varies greatly among chemicals and other hazardous agents in type, quantity, and quality, it is not possible to describe the WoE evaluation in other than relatively general terms. It is thus not unexpected that WoE judgements in particular cases can vary among experts and that consensus is sometimes difficult to achieve'' (NAS, 2009) (Ref. 3). The following is a brief description of how WoE is used at EPA, serving as an example of successful application of WOE in making the scientific determinations.

EPA utilizes the WoE approach in existing programs including IRIS and the Endocrine Disruptor Screening Program among others, and in the classification of carcinogens. In the 1999 Guidelines for Carcinogen Risk Assessment (Ref. 4) EPA refers to the WoE approach as ''. . . a collective evaluation of all pertinent information so that the full impact of biological plausibility and coherence is adequately considered (Ref. 5). The Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) referred to the WoE approach as ''. . . a process by which trained professionals judge the strengths and weaknesses of a collection of information to render an overall conclusion that may not be evident from consideration of the individual data'' (Ref. 6).

WoE is the process for characterizing the extent to which the available data support a hypothesis that an agent causes a particular effect (Ref. 4 and 5). This process involves a number of steps starting with assembling the relevant data, evaluating that data for quality and relevance, followed by an integration of the different lines of evidence to support conclusions concerning a property of the substance. WoE is not a simple tallying of the number of positive and negative studies, but rather it relies on professional judgment. The significant issues, strengths, and limitations of the data and the uncertainties that deserve serious consideration are presented, and the major points of interpretation are highlighted.

This WoE analysis is conducted on a case-by-case basis by first assembling and assessing the individual lines of evidence and then performing an integrated analysis of those lines of evidence. All data considered in the WoE analysis need to be documented and scientifically acceptable. A WoE analysis typically begins with a careful evaluation of each individual study. The process of evaluating the individual lines of evidence includes assembling the data, evaluating that data against current acceptance and quality criteria, and presenting the conclusions regarding the results for each study. The reviews of the available studies need to be transparent about what studies were considered or not, and how the quality of a study was judged.

After assembling and assessing the individual lines of data, an integrated analysis is performed. This means the results from all scientifically relevant published or publically available peer-reviewed studies, which are of sufficient quality and reliability, are evaluated across studies and endpoints into an overall assessment. In general, the WoE analysis examines multiple lines of evidence considering a number of factors, including for example the nature of the effects within and across studies, including number, type, and severity/magnitude of effects and strengths and limitations of the information.

A summary WoE narrative or characterization generally accompanies the detailed analysis of the individual studies and the integrative analysis of the multiple lines of evidence. Inclusion of a WoE narrative is common in WoE assessments and judgments (Ref. 4 and 7). The narrative/characterization is intended to be transparent and allow the reader to clearly understand the reasoning behind the conclusions. The narrative will generally explain the selection of the studies or effects used as the main lines of evidence and relevant basis for conclusions. The overall strength of the evidence supporting a conclusion from the WoE evaluation needs to be described.

The National Toxicology Program of the National Institute of Environmental Health Sciences has developed a tool called ''systematic review'' to assist in WoE evaluations particularly for hazard identification (*https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html*). This tool uses a defined set of processes to identify, select, critically assess, and synthesize evidence to arrive at a hazard conclusion for a chemical. It is designed to enhance transparency and informs scientific judgments. The evidence synthesis step involves considering factors that decrease confidence in the body of evidence for a particular health endpoint (*e.g.* risk of bias, inconsistencies across studies, imprecision) as well as factors that increase confidence (*e.g.* magnitude of the effect, residual confounding, consistency). By evaluating study design (*e.g.,* consistent with study guidelines issued by OECD, and test guidelines issued by the Office of Chemical Safety and Pollution Prevention), and study quality (*e.g.,* studies that comply with Good Laboratory Practices (GLP) like those applicable generally (*https://www.federalregister.gov/documents/2016/08/24/2016–19875/good-laboratory-practice-for-nonclinical-laboratory-studies*) and those issued by EPA for studies submitted under TSCA and FIFRA (*https://www.epa.gov/compliance/good-laboratory-practices-standards-compliance-monitoring-program*)), and integrating negative data (and consideration of the quality of those data), the confidence in hazard conclusions can be increased.

The NIEHS systematic review tool is one example of a documented systematic review approach. EPA believes the proposed risk evaluation process generally reflects the use of systematic review approaches that are appropriate for the types and quantity of information used in a chemical risk evaluation. EPA requests comment on this view. EPA is also requesting comment on the need for regulatory text requiring the use of specific elements of a systematic review approach for hazard identification, including the appropriateness of specific elements that might be included and/or concerns about codifying such an approach.

4. Timeframe. TSCA requires that the risk evaluation process last no longer than three years with a possible six-month extension. 15 U.S.C. 2605(b)(4)(G).

5. Opportunities for public participation. The statute requires that the Agency allow for at least one 30 day public comment period on the draft risk evaluation, prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

6. Metals and metal compounds. When evaluating metals or metal compounds, EPA must ''use'' the March

2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 8) or a successor document that addresses metals risk assessment and is peer-reviewed by the Science Advisory Board.

7. Other statutory requirements. TSCA imposes new requirements on EPA in a number of different areas that EPA is not proposing to incorporate or otherwise address in this proposed rule. For example, amendments to TSCA section 4 require EPA to ''. . . reduce and replace, to the extent practicable, [. . .] the use of vertebrate animals in the testing of chemical substances . . .'' and to develop a strategic plan to promote such alternative test methods. 15 U.S.C. 2603(h). Likewise, TSCA section 26 requires, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, that EPA uses certain scientific standards and bases those decisions on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). While these requirements are relevant to the risk evaluation of chemical substances, EPA is not obliged to repeat them in this proposed rule. As statutory requirements, they apply to EPA's decisions under TSCA section 6. Moreover, in contrast to TSCA section 6, Congress has not directed EPA to implement these other requirements ''by rule;'' it is well-established that where Congress has declined to require rulemaking, the implementing agency has complete discretion to determine the appropriate method by which to implement those provisions.

C. EPA Risk Assessment

Since EPA's inception, human health and ecological risk assessment has informed decisions made to protect humans and the environment. Risk assessments performed by the Agency inform a broad range of regulatory decisions, and, over time, the scientific approaches and methods employed for these risk assessments have evolved. In developing and refining risk assessment processes, frameworks, and guidance documents, EPA has incorporated recommendations from expert technical panels, internal and external peer reviews, and a number of influential reports from the National Academy of Sciences (NAS) National Research Council (NRC) including Risk Assessment in the Federal Government (1983) (Ref. 9), Science and Judgement in Risk Assessment. (1994) (Ref. 10), Understanding Risk: Informing Decisions in a Democratic Society (1996) (Ref. 11), Toxicity Testing in the 21st Century: A Vision and a Strategy (2007) (Ref. 12), Phthalates and Cumulative Risk Assessment: The Tasks Ahead (2008) (Ref. 8), and Science and Decisions: Advancing Risk Assessment (2009) (Ref. 3). Specifically, the NAS NRC Science and Decisions Report (Ref. 3) recommended that EPA focus on the important roles of scoping or problem formulation so that a risk assessment will serve a specific and documented purpose. An additional recommendation encouraged EPA to develop risk assessments that are well-tailored to the problems and decisions at hand so that they can inform the decision-making process in the most meaningful way. EPA has evaluated, and will continue to evaluate chemical risks in a manner that is best suited for the particular chemical substance, including its manufacture, processing, formulation, uses, and disposal, and the evaluations may vary as necessary to best characterize potential risks related to the chemical substance under review.

As stated, TSCA requires EPA to evaluate risk to relevant potentially exposed or susceptible subpopulations identified by EPA as relevant to the risk evaluation under the conditions of use. 15 U.S.C. 2605(b)(4)(A). Although this was added as a component of the newly amended law, this will not be a new consideration for the Agency; for example, see EPA's Policy on Evaluating Health Risks to Children (1995) (Ref. 14). The Agency has evaluated the risk of chemical substances to all sectors of the population, with particular attention to workers, indigenous peoples, pregnant women, children, infants, the elderly, environmental justice communities, and fence-line communities, among others. The Agency utilizes a number of existing guidance documents (including but not limited to Ref. 15, 16, 17, 18, and 19) to evaluate risk at various life stages, and will use and refine these processes to protect the most vulnerable.

1. Differences between previous EPA risk assessments under TSCA and proposed new risk evaluations. In this proposed rule, EPA does not propose a new method of risk evaluation, but builds upon existing and proven methodologies for evaluating risk. Also as required by the statute, the rule includes opportunities for public participation, statutory deadlines, necessary components of a risk evaluation, and methods for manufacturer requested risk evaluation. Above and beyond the statute, the proposed rule provides an additional opportunity for public participation, added detail as to components of the scope, hazard and exposure assessments, risk characterization, and increases transparency in the risk evaluation process. EPA requests comment on whether and how the proposed rule could provide additional transparency, public accountability, opportunities for public participation, or incorporation of statutory deadlines.

There are several key differences between previous chemical risk assessments conducted under TSCA and the new risk evaluation process mandated by TSCA amendments and established under these proposed regulations. These differences include considerations of conditions of use, timelines, and determination of unreasonable risk, and are discussed in more detail under those topics in this unit. This proposed rule and procedures described herein apply to risk evaluations conducted under TSCA, and do not apply to risk evaluations conducted by EPA pursuant to other statutes or programs.

2. Conditions of use. Prior to the amended TSCA, EPA was free to and did conduct risk assessments on selected uses of chemical substances. In contrast, EPA interprets the amended TSCA as requiring that risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities that constitute the conditions of use within the meaning of TSCA section 3. That is to say, a risk evaluation must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance. This issue has been the subject of considerable discussion since the enactment of the new law, and EPA acknowledges that different readings of the law may be possible. For example, TSCA section 6(b)(4)(D) requires EPA to identify the conditions of use that the Agency expects to consider in a risk evaluation, suggesting that EPA does not need to consider all conditions of use.

Overall, the statutory text and purpose are best effectuated through a more encompassing reading. TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether ''a chemical substance'' presents an unreasonable risk of injury to health or the environment ''under the conditions of use.'' The evaluation is on the chemical substance—not individual conditions of use—and it must be based on ''*the* conditions of use.'' In this context, EPA believes the word ''the'' is best interpreted as calling for evaluation that considers all conditions of use. First, if EPA were free to base its determination of whether a chemical substance, as a whole, presents an unreasonable risk or injury (as the statute requires) on merely a subset of individual uses, it could, for example,

determine that a chemical substance with 10 known uses does not present an unreasonable risk of injury based on an evaluation of a single one of those uses, with no further obligation to evaluate the remaining uses within the three-year statutory deadline. This is a strained reading of the commands to determine whether the chemical substance presents an unreasonable risk, under the conditions of use, and to complete that evaluation ''for a chemical substance'' within three years of initiation. See 15 U.S.C (b)(4)(G)(i).

Second, a major objective of the new law is to require EPA to systematically evaluate existing chemical substances to determine whether or not they present unreasonable risk, and, if necessary, regulate them based on the results of the evaluation. Given the large number of existing chemical substances, it would not be feasible to complete risk evaluations on any significant number of them if EPA were to continually need to re-evaluate chemical substances based on different subset of uses. Rather the law's purposes will be best fulfilled by judging in a comprehensive way whether a chemical substance, under the known, intended, and reasonably foreseen uses and other activities, presents an unreasonable risk; ensuring through regulation that it does not present an unreasonable risk, if necessary; and then presumptively being done with that chemical substance (pending re-prioritization for some unforeseen reason). Finally, EPA notes that, if the law is read as allowing EPA to select particular conditions of use, it provides no criteria for EPA to apply in making such a selection.

Given these considerations, the instruction in TSCA section 6(b)(4)(D) for the Agency to identify the conditions of use it expects to consider in a risk evaluation is best read as directing the Agency to identify the uses and other activities that it has determined constitute the conditions of use, not as a license to choose among conditions of use.

Concerns have been raised about EPA's ability to meet the statutory risk evaluation deadlines if all conditions of use must be considered. Concerns have also been raised about ensuring that EPA can act promptly to address any unreasonable risks identified for particular conditions of use. EPA acknowledges that this will be challenging but based on the procedures outlined in this proposal, expects it will be manageable. First, a use or other activity constitutes a condition of use under the definition only if EPA determines that it does. EPA has authority to exercise judgment in making its determination of whether a condition of use is known, intended, or reasonably foreseen. Moreover, in this proposed rule EPA proposes to ''lock down'' the conditions of use included in a risk evaluation at the time of scoping, by providing opportunity for comment on the scoping document and specifying that any objections to the draft scope document are waived if not raised during this process. It will not be practicable to meet the statutory deadlines if stakeholders are free to identify additional conditions of use later in the process—for example, on the proposed risk determination.

As explained elsewhere in this preamble, EPA also generally intends to initiate risk evaluation on a chemical substance only when EPA determines that sufficient reasonably available information exists to complete the evaluation, and when it has already identified all of the conditions of use. As also explained elsewhere in this preamble, under certain circumstances EPA may expedite an evaluation for a particular condition of use to move more rapidly to risk management under TSCA section 6(a).

Finally, the proposed rule provides that EPA will rely on a combination of information, accepted science policies (*e.g.,* defaults and uncertainty factors), models and screening methodologies in conducting risk evaluations, with considerations of evolving science and technology. It further provides that the balance of information, science policy decisions, models, and screening methodologies used in risk evaluation will be informed by the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluations, and by the extent to which the generation of additional information is warranted by the reduction in uncertainty that the information would afford in determining whether a chemical substance presents an unreasonable risk of injury to health or the environment.

In this regard, EPA is also proposing to require that the components of its risk evaluations will be ''fit for purpose.'' All conditions of use will not warrant the same level of evaluation, and EPA expects it may be able to reach conclusions without extensive or quantitative evaluations of risk. For example, lower-volume or less dispersive uses might receive less quantitative, data-driven evaluations than uses with more extensive or complicated exposure patterns. Consistent with EPA's current practice in conducting risk assessments, technically sound risk determinations can be made, consistent with the best available science, through a combination of different types of information and other approaches.

In sum, Congress intended to create obligations that EPA can actually meet, and EPA intends to conduct risk evaluations in a way that is manageable given the statutory deadlines.

3. Timelines and guidance regarding assessing risks of existing chemical substances. Prior to the amended TSCA, EPA was not required to evaluate or manage the risk of the thousands of existing chemical substances grandfathered in under the 1976 Act. As discussed previously, the amended TSCA affirmatively requires EPA to evaluate existing chemical substances more quickly, instructs EPA on how many of these chemical substances the Agency must evaluate at any given time, and places time limits on when these evaluations must be completed. 15 U.S.C. 2605(b)(2)–(4).

4. Determination of unreasonable risk. Under TSCA section 6(b) (15 U.S.C. 2605(b)(4)(B)), EPA must establish a risk evaluation process to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. Prior to the passage of the amended TSCA, chemical substance risk assessments did not include a determination of unreasonable risk. This step was reserved for risk management rulemaking. The amended statute now requires that a risk evaluation include a risk assessment as well as the EPA's determination of unreasonable risk, and, most significantly, requires that this determination be independent of cost or other non-risk factors. 15 U.S.C. 2506(b)(4)(A) and (F)(iii).

In general, EPA may weigh a variety of factors in determining unreasonable risk. These factors include, but are not limited to, characterization of cancer and non-cancer risks (including margins of exposure for non-cancer risks), the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard), the irreversibility of hazard, uncertainties, and estimates of cumulative exposure. Because of the case-by-case nature of each of these factors EPA has purposely not proposed a definition of unreasonable risk in this rule. However, EPA is specifically requesting comments on whether EPA should define unreasonable risk in the final rule. If so, acknowledging that the statute precludes consideration of costs and other non-risk factors at this step, what factors should EPA consider in making such a determination?

5. Manufacturer-requested evaluations and draft risk evaluations by interested persons. The newly

amended TSCA requires that a portion of ongoing risk evaluations be conducted on chemical substances requested by manufacturers ''in a form and manner and using criteria'' EPA prescribes by rule. 15 U.S.C. 2605(b)(4)(C)(ii),(E)(i). The statute also requires EPA to develop guidance (which will be forthcoming) to assist interested persons in submitting draft risk evaluations, and requires EPA to consider such submitted drafts. 15 U.S.C. 2625(l)(5).

D. Stakeholder Feedback

On August 9, 2016, EPA held a one-day public meeting to obtain public comment and feedback regarding the development and implementation of the risk evaluation rule. The meeting began with an explanation of how the Agency currently conducts risk assessments (see *https://www.epa.gov/sites/production/files/2016-08/documents/risk_evaluation_9_august_2016.pdf*). The remainder of the day was reserved for public comment. Each commenter was provided four minutes to comment and there was a total of 47 oral comments on the risk evaluation rule. Additionally, EPA opened a docket for submission of written comments and received 57 comments, many of which were from the same commenters at the public meeting. These comments, and a transcript of the meeting are accessible in the meeting's docket, identified by Docket ID No. EPA–HQ–OPPT–2016–0399, which is available online at *https://www.regulations.gov/*.

The commenters included industry, environmental groups, academics, private citizens, trade associations, and health care interest groups and representatives. The comments were very informative for both rule development and risk evaluation implementation. While not all of the comments are captured here, there were a number of themes that emerged. Overall, there was a general expression of support for the new law and EPA's inclusive approach to implementation. Many of the commenters agreed the rule has the potential to increase transparency in EPA's chemical substance risk evaluation process. Many urged the Agency to work towards this goal, while creating an open scientific dialogue.

Questions arose about how the Agency will determine ''unreasonable risk'' and implement TSCA section 26 requirements including ''best available science'' and ''weight of scientific evidence.'' Some suggested that EPA should codify in this rule the meaning of these terms along with other details of the risk evaluation process. Due to changes in the law, manufacturers are now able to submit their own draft risk evaluations. Commenters noted that if these submitted evaluations are to be equivalent as Agency draft risk evaluations, having specific criteria, such as specific types of exposure and hazard information would ensure the Agency and the manufacturers were held to the same standard. Stakeholders also suggested that holding a public comment period for the draft risk evaluation scope would increase the transparency of each risk evaluation early in the process and allow the public to comment on any data gaps or discrepancies.

Other stakeholders urged the Agency to reserve specific scientific processes regarding hazard and exposure information for Agency guidance and discretion, suggesting the rule should address only the process and procedure. This approach would allow the Agency to be flexible and adapt to the changing science of risk evaluation and the science that informs risk evaluation.

A number of commenters spoke about the statute's requirement that the Agency determine the specific risk to ''potentially exposed or susceptible subpopulation[s]''. Although the law defines this term to include ''infants, children, pregnant women, workers, or the elderly,'' many encouraged the Agency to consider expanding the definition to include for example: environmental justice communities, Arctic communities, American Indian communities, communities with little access to preventative health-care, subsistence fishers, and fence-line communities. There were a number of stakeholders who encouraged the Agency to work with the Occupational Safety & Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and the Consumer Product Safety Commission (CPSC), among other federal agencies, to better protect against occupational and consumer exposures. Also regarding exposure, stakeholders encouraged the examination of cumulative and low dose exposures in risk evaluations, which are not specifically mentioned in the new statute.

A number of commenters emphasized the need for EPA to maximize transparency throughout the evaluation process. The EPA received a number of comments about the science used to inform individual risk evaluations, including the types of data, models, policy assumptions (*e.g.,* default factors) and computational approaches. A number of commenters argued that a lack of data does not equate to a lack of risk. Stakeholders encouraged the Agency to engage with industry to obtain hazard and exposure data and to utilize the new order authority allowed under the law (TSCA section 4). Commenters suggested an increased use of EPA's Office of Research and Development (ORD) and internationally accepted data, models, and products. A number of stakeholders expressed their support for the new provision in the law that requires the Agency to reduce and replace vertebrate testing (TSCA section 4(h)) in obtaining chemical substance hazard and exposure data.

EPA considered all of these comments in the development of this proposed rule, and welcomes additional feedback from stakeholders on the proposed process and requirements presented in this document.

III. The Proposed Rule

A. Policy Objectives

The risk evaluation process under TSCA is ultimately how EPA will determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. The overall objective of this action is to propose to codify the process by which the Agency evaluates risk from chemical substances for purposes of TSCA section 6. In this proposed rule, the Agency details those components of TSCA risk evaluation and key factors that EPA deems are necessary to consider in each risk evaluation to ensure that the public has a full understanding of how risk evaluations will be conducted. However, EPA is not proposing to establish highly detailed provisions that will address every eventuality or possible consideration that might arise. Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.

B. Interagency Collaboration

EPA recognizes that other Federal agencies may be able to provide important use, exposure and hazard information that is likely to be relevant to a risk evaluation of chemical substances. EPA is committed to interagency engagement and dialogue throughout its risk evaluation process, including data sharing, information requests, and consultation regarding specific chemicals of interest. As such,

EPA has reached out to other agencies, inviting them to join the agency in an open and collaborative dialogue. EPA intends to continue and expand its interagency collaboration efforts for chemicals management and risk evaluations under TSCA.

To coordinate with other agencies on TSCA implementation generally, EPA intends to continue to use—and expand where appropriate—existing interagency groups, such as the OMNE (OSHA–MSHA–NIOSH–NIEHS–EPA) Committee and the National Science and Technology Council (NSTC)'s Committee on Environment, Natural Resources, and Sustainability's new Toxicity Assessment Committee. EPA is also committed to interagency engagement at the working level on individual chemical evaluations.

To ensure that such collaboration can occur in a timely manner when needed, EPA intends to initiate interagency consultation through the existing mechanisms early in the process, and document these measures in the scope document. However, EPA is concerned that imposing a single, pre-determined consultation step might lead to an overly bureaucratic process that could limit or complicate ongoing collaboration efforts, and so is not proposing to codify any particular process in this regulation.

C. Scope of Evaluations

TSCA requires risk evaluations to determine whether or not a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, with conditions of use being defined as ''the circumstances, as determined by the EPA, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.'' 15 U.S.C. 2602(4).

Although some of the commenters during the public meeting suggested that EPA could evaluate a specific use of a chemical substance, EPA is not choosing to adopt such an interpretation, for the reasons explained previously. Also, EPA recognizes that under certain circumstances it may be necessary to expedite an evaluation for a particular condition of use to move more rapidly to risk management under TSCA section 6(a) (15 U.S.C. 2605(a)): this could include a situation in which a single use presented an unreasonable risk of injury for the population as a whole or for a susceptible subpopulation (*e.g.,* one use results in risks that EPA would determine unreasonable regardless of the risk posed by other uses). However, in any case where EPA would find it necessary to pursue a risk evaluation in phases, the Agency will still complete the full risk evaluation on all identified conditions of use within the statutory 3-year deadline. Therefore, relying on this discretion, EPA is proposing to explicitly recognize its authority to complete risk evaluations in phases, and to manage unreasonable risks as they are identified through those phases under TSCA section 6(a) in the regulation.

D. Definitions

TSCA defines a number of key terms necessary for interpretation of the new law. The definitions within the law apply to this proposed rule. EPA has also included some additional definitions in the proposed rule for further clarification; these are noted and defined later in this document. The law requires EPA to evaluate risk to ''potentially exposed or susceptible subpopulation[s],'' and although the law elaborates on this phrase, EPA is proposing to expand the definition for TSCA purposes. TSCA states that ''the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.'' 15 U.S.C. 2602(12). EPA is proposing to incorporate the phrase ''including but not limited to'' before the specific subpopulations identified in the statutory definition, to further clarify that EPA may identify additional subpopulations, where warranted. As suggested by the statute, EPA is also proposing to include specific authorization for EPA to consider both intrinsic (*e.g.,* life stage, reproductive status, age, gender, genetic traits) and acquired (*e.g.,* pre-existing disease, geography, socioeconomic, cultural, workplace) factors when identifying this population.

TSCA section 26(k) (15 U.S.C. 2625(k)) states that in carrying out risk evaluations, EPA shall consider information that is ''reasonably available,'' but the statute does not further define this phrase. EPA is proposing a definition for ''reasonably available'' to mean existing information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. Generally speaking, EPA does not consider information that has not yet been generated, as reasonably available, because it will typically not be feasible for EPA to require significant chemical testing and receive and assess those test results during the three to three and a half year window allotted for risk evaluation. Accordingly, EPA intends to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation (indeed, prior to initiating prioritization). EPA also generally intends to use its authority under TSCA to require the development of new information, as necessary, prior to risk prioritization.

TSCA requires EPA, as a part of the risk evaluation, to document whether the Agency has considered aggregate or sentinel exposure, and the basis for that decision. 15 U.S.C. 2605(b)(4)(F)(ii). These terms are not defined in the law, so EPA has proposed a definition for aggregate exposure that is consistent with current Agency policies and practices. ''Aggregate exposure'' means the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (Ref. 20). ''Sentinel'' means the exposure(s) of greatest significance, which may be the maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof). Although sentinel exposure is not a novel way of characterizing exposure, this is a new term for EPA.

Other terms defined in the proposed rule are designed to provide clarity regarding the science that will be used to conduct an evaluation. ''Pathways'' of exposure refers to the mode through which one is exposed to a chemical substance, including but not limited to: food, water, soil, and air (Ref. 20). ''Routes'' of exposure refer to the particular manner which a chemical substance may contact the body, including absorption via ingestion, inhalation, or dermally (Ref. 20). The statute requires EPA to consider ''the extent to which the variability and uncertainty . . . are evaluated and characterized.'' 15 U.S.C. 2625(h). EPA is adopting definitions for both ''variability'' and ''uncertainty'' from existing Agency guidance. ''Uncertainty'' means the imperfect knowledge or lack of precise knowledge either for specific values of interest or in the description of a system (Ref. 21). ''Variability'' means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population (Ref. 21).

E. Timing of Risk Evaluations

As indicated, the statute requires EPA to complete risk evaluations within three years, with the possibility of a six month extension beyond the three year timeframe. This proposed rule simply adopts these timeframes without modification or elaboration. EPA acknowledges this is a relatively short timeframe, and, as discussed elsewhere in this preamble, is proposing to adopt other procedures that will allow the Agency to meet these deadlines.

F. Chemical Substances for Risk Evaluation

As identified previously, chemical substances that will undergo risk evaluation can be put into three groups: (1) The first ten chemical substances the Agency is required to identify within the first 180 calendar days of enacting the amendments to TSCA (15 U.S.C. 2605(b)(2)); (2) the chemical substances determined as High-Priority Substances through the prioritization process proposed in a separate rulemaking; and (3) requested chemical substances submitted by manufacturers that meet the criteria for EPA to conduct an Agency risk evaluation.

G. Process for Manufacturer Requested Risk Evaluations

TSCA allows a manufacturer or group of manufacturers to submit requests for Agency conducted risk evaluations for chemical substances that they manufacture. EPA is proposing the necessary components of the request in the proposed regulatory text. EPA is proposing to require that manufacturers demonstrate in their request that there is sufficient, reasonably available information for the Agency to conduct a risk evaluation on the chemical substance under the conditions of use. EPA must complete any manufacturer-requested risk evaluation that it determines meets the criteria within the statutory three years. Unlike those chemical substances that have come through the prioritization process, manufacturer-requested chemical substances have not undergone initial risk screening and therefore EPA will not assign such chemicals a high- or low-priority designation. The purpose of the requirements proposed as the necessary components of the request, is to allow the Agency to determine whether sufficient information is ''reasonably available'' for EPA to complete a risk evaluation of the requested chemical under the conditions of use, as that term is defined under TSCA section 3.

EPA is proposing to require a manufacturer to submit a list (*e.g.,* citations) of the reasonably available information on hazard and exposure for all the conditions of use. EPA is not requesting manufacturers submit copies of the cited information. Manufacturers must include a commitment to provide EPA any referenced data if they are not publicly available, and must certify that the information submitted is accurate and complete. EPA will not accept a manufacturer request where any of the relevant data is not in the possession of the requestor but is with another entity.

Consistent with TSCA section 6(b)(4)(E)(iii), EPA will prioritize requests where there is evidence that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and is therefore proposing to allow (but not require) manufacturers to include any evidence to support such a finding. Following this required initial prioritization, EPA is proposing to further prioritize chemical substances for risk evaluation based on initial estimates of exposure(s) and/or hazard(s) under one or more conditions of use or any other factor that EPA determines may be relevant. In general, EPA plans to prioritize those chemical substances where there is evidence of relatively high risk over those with less evidence of risk.

Instructions for submitting CBI are also included in the proposed rule. EPA believes that TSCA section 14(c)(3) is best read as requiring upfront substantiation of non-exempt CBI claims. In addition, EPA believes the obligation to review all non-exempt chemical identification claims and 25 percent of all other non-exempt claims will be best effectuated by requiring substantiation at the time of submission.

Chemical substances that EPA has prioritized through the prioritization process (proposed in a separate rulemaking), are subject to two separate public comment periods prior to the completion of the prioritization process. EPA expects that these comment periods will ensure that EPA has the necessary information to evaluate the chemical substances, including information on all conditions of use. Consequently, in order to ensure that chemical substances subject to manufacturer requests undergo risk evaluation only if the available information is comparable to what EPA will identify or generate through the measures identified in the proposed prioritization framework rule, EPA is proposing opportunities to collect additional information from the public.

Upon receipt of the request, EPA is proposing to verify that the request is facially valid, *i.e.,* that information has been submitted that is consistent with the regulatory requirements. EPA is proposing that within 30 business days of a receiving a facially valid request, EPA will submit for publication an announcement of the receipt of the request in the **Federal Register**, open a docket for the request, and provide no less than a 30 calendar day comment period, to allow the public to identify and/or submit any reasonably available information regarding hazard, exposure, potentially exposed population(s) and subpopulation(s), and conditions of use that may help inform a risk evaluation, including identifying information gaps. The requesting manufacturer may also submit any additional material during this time.

Within 9 months after the end of the comment period, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the regulatory criteria and will notify the manufacturer(s) accordingly. This time will allow EPA to develop the equivalent of a conceptual model to describe actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, or disposal. If EPA determines that the request is compliant (*i.e.,* it has the required information necessary for conducting a risk evaluation), EPA will begin the risk evaluation process consistent with TSCA section 6(b)(4)(E)(i). If the request is found insufficient EPA will identify the information that would be necessary to conduct the risk evaluation in its notification to the manufacturer. The manufacturer will have 60 calendar days from receipt of EPA's determination to submit the additional information. EPA will consider the request withdrawn if the manufacturer(s) fails to submit the additional information identified. The process for conducting the risk evaluation will otherwise be identical to the process for those chemical substance identified as a High-Priority Substance through the Prioritization Process, which is addressed in a separate proposed rule.

H. Risk Evaluation General Provisions

1. Agency guidance. EPA has a number of existing guidance documents that inform Agency risk assessment.

EPA has been using risk assessments to characterize the nature and magnitude of health risks to humans and ecological receptors from chemical contaminants and other stressors that may be present in the environment since its inception. Over the years, EPA has worked with the scientific community and other stakeholders to develop a variety of guidance, guidelines, methods and models for use in conducting different kinds of assessments. A compendium of existing Agency guidance related to risk assessments is maintained at *https://www.epa.gov/risk/risk-assessment-guidelines*. A compendium of guidance, databases and models used for assessing pesticide risks is available at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks*, and information about available predictive models and tools for assessing chemicals under TSCA can be found at *https://www.epa.gov/tsca-screening-tools*. Each of these Web sites identify and link to a number of written guidance documents, tools and models. Rather than starting anew, EPA intends to take advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program.

Since the law requires the development of additional ''policies, procedures, and guidance the Administrator determines are necessary'' to carry out the process in TSCA (15 U.S.C. 2625(l)). EPA may also develop additional guidance(s) for risk evaluation in the future.

2. Categories of chemical substances. TSCA provides EPA with authority to take action on categories of chemical substances: groups of chemical substances which are, for example, similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment. Although the proposed rule most often references ''chemical substances,'' EPA is also proposing to include a clear statement in the regulation that nothing in the proposed rule shall be construed as a limitation on EPA's authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can prioritize and evaluate categories of chemical substances.

3. Information and information sources. As discussed, the timeframe for completing risk evaluation is compressed. For those chemical substances chosen by EPA to undergo the risk evaluation process, EPA expects to only initiate the process when EPA has determined that most of the information necessary to complete the evaluation is reasonably available, which in most cases means the information already exists. As appropriate, however, EPA will exercise its TSCA information collection, testing, and subpoena authorities, including those under TSCA sections 4, 8, and 11(c) to develop the information needed for a risk evaluation. Pursuant to TSCA section 8(e), the law requires that any person who manufacturers, processes, or distributes in commerce a chemical substance or mixture and who obtains information which supports the conclusion that this substance presents a substantial risk of injury to health or the environment, shall immediately inform the Agency.

To conduct a risk evaluation, EPA will rely on a combination of information, models, screening methods, and accepted science policies, which include defaults, reasonable estimates, and uncertainty factors, in addition to considering information generated from evolving science and technology. EPA expects to obtain scientific advice from the Science Advisory Committee on Chemicals, which the Agency is required to develop and convene under TSCA section 26(o). In compliance with the statute, EPA will work to reduce and replace, to the extent practicable, the use of vertebrate animals in testing chemical substances as outlined in TSCA section 4(h).

I. Risk Evaluation Steps

1. Scope. The first step of a risk evaluation is the development of the scope. In compliance with the statute, the scope will identify the conditions of use, hazards, exposures, and any potentially exposed or susceptible subpopulations that the EPA expects to consider. EPA is also proposing to include additional information in the scoping document, including any models, screening methods, and any accepted science policies expected to be used during the risk evaluation. EPA is further proposing to include a conceptual model that will describe the actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, to release or disposal. Also included will be an analysis plan, which will identify the approaches and methods EPA plans to use to assess exposure, effects, and risk, including associated uncertainty and variability, as well as a strategy for approaching science policy decisions (*e.g.,* defaults or uncertainty factors).

The announced availability of the final scope will be published in the **Federal Register** within six months of the initiation of the risk evaluation. Although not required under the statute, EPA has proposed to provide a draft scope for a 45 calendar day public comment period during this six month period. EPA welcomes all public participation, but specifically encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. That said, EPA expects to use the comment periods during the prioritization process to reduce the likelihood of significant comments on the draft scope. Consequently, the proposed rule makes clear that all comments that could be raised on information and approaches presented in the scope must be presented during this comment period. Any issues related to scope not raised in comments at this time cannot form the basis for an objection or challenge in a future administrative or judicial proceeding. This is a well-established principle of administrative law and practice, see, *e.g.,* Nuclear Energy Institute v. EPA, 373 F.3d 1251, 1290–1291 (D.C. Cir. 2004), and the need for such a provision is reinforced by the statutory deadlines under which EPA must operate for completing TSCA risk evaluations. Note that EPA is not proposing to preclude parties from raising newly discovered information, or from raising issues that could not have been fairly raised during this comment period. Rather, EPA seeks merely to prevent parties from delaying the risk evaluation by withholding information or by providing it piecemeal.

2. Hazard assessment. In compliance with TSCA section 6(b)(4)(F), EPA is proposing that a hazard assessment be conducted on each chemical substance or category. A hazard assessment identifies the types of adverse health or environmental effects that can be caused by exposure to some agent in question, and to characterize the quality and weight of evidence supporting this identification. Hazard Identification is the process of determining whether exposure to a stressor can cause an increase in the incidence of specific adverse health or environmental effects (*e.g.,* cancer, developmental toxicity).

This hazard assessment may include, but may not be limited to, evaluation of the potential toxicity of the chemical substance with respect to cancer, mutation, reproductive, developmental, respiratory, immune, metabolic, and cardiovascular impacts, and

neurological impairments. The assessment will evaluate effects at life stage(s) most appropriate for a receptor target. The hazard assessment will consider the dose or concentration and resulting effect or response. Potential information sources that may support the health assessment include but are not limited to: Human epidemiological studies; *in vivo* and/or *in vitro* laboratory studies; mechanistic or kinetic studies in a variety of test systems, including but not limited to toxicokinetics and toxicodynamics, computational toxicology; data from structure-activity relationships, high-throughput assays, genomic response assays, and ecological field data. Specifically, for human health hazards, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope and use appropriate combination, if available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing health effects to the population, and any other relevant, scientifically valid information or methodology. In an environmental hazard assessment, the relationship between the chemical substance and the occurrence of an ecological response will be evaluated using field or laboratory data, modeling strategies, and species extrapolations.

Where possible, a hazard assessment also will include a dose-response assessment. A dose-response relationship describes how the likelihood and severity of adverse health effects (the responses) are related to the amount and condition of exposure to an agent (the dose provided). The same principles generally apply for studies where the exposure is to a concentration of the agent (*e.g.,* airborne concentrations applied in inhalation exposure studies or water or other media concentrations for ecological exposure studies), and the resulting information is referred to as the concentration-response.

3. Exposure assessment. Pursuant to TSCA section 6(b)(4)(F), EPA, where relevant, will take into account the likely duration, intensity, frequency, and number of exposures under the conditions of use in an exposure assessment. An exposure assessment includes some discussion of the size, nature, and types of individuals or populations exposed to the agent, as well as discussion of the uncertainties in this information. Exposure can be measured directly, but more commonly is estimated indirectly through consideration of measured concentrations in the environment, consideration of models of chemical transport and fate in the environment, and estimates of human intake or environmental exposure over time.

Using reasonably available information, exposures will be estimated (usually quantitatively) for the identified conditions of use. For human health exposure, the assessment would consider all potentially exposed or susceptible subpopulation(s) identified in the scope and utilize any combination, as available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing exposures to the population, measurements in human tissues or relevant environmental or exposure media, and any other relevant, scientifically valid information or methodology. In an environmental health exposure assessment, the interaction of the chemical substance with any ecological characteristics identified in the scope will be characterized and evaluated.

4. Risk characterization. TSCA requires that a risk evaluation ''integrate and assess available information on hazards and exposures''. (15 U.S.C 2605(b)(4)(F). A risk characterization conveys the risk assessor's judgment as to the nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made. Risk characterization takes place for both human health risk assessments and ecological risk assessments.

In practice, each component of the risk assessment (*e.g.* hazard assessment, dose-response assessment, exposure assessment) has an individual characterization written to carry forward the key findings, assumptions, limitations, and uncertainties. The set of these individual characterizations provide the information basis to write an integrative risk characterization analysis. The final, overall risk characterization thus consists of the individual component characterizations plus an integrative analysis.

Each risk evaluation will quantitatively and/or qualitatively estimate and characterize risk for the identified populations and ecological characteristics under the conditions of use. The risk characterization will also describe whether aggregate or sentinel exposures were considered and provide the evidence and information to support the consideration.

In the risk characterization, EPA will further carry out the obligations under TSCA section 26(h) (15 U.S.C 2625(h)); for example, by assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. EPA also may exercise it discretion to include a discussion of any alternative interpretation of results generated from the risk evaluation. For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

5. Peer review. For each risk evaluations conducted on chemicals identified pursuant to TSCA section 6(b)(4)(A), EPA will conduct peer reviews using the guidance provided in executive branch peer review directives included in the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin) (Ref. 22) and the guidance set forth in the EPA Peer Review Handbook (2015) (Ref. 23) or its updates.

The goal of the peer review process is to obtain independent review from experts who have not contributed to its development. According to EPA's peer review policy, peer review of all scientific and technical information that is intended to inform or support Agency decisions is encouraged and expected. Both the EPA Peer Review Handbook and the OMB Bulletin provide standards for when and how to conduct peer review on science documents. The documents do not contemplate that peer review is necessary for every document or risk assessment, but is expected to occur for those documents that have either:

- Influential scientific information: scientific information that the Agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions, or
- Highly influential scientific assessment: a subset of influential scientific information that could have a potential impact of more than $500 million in any year on either the public or private sector or is novel, controversial, or precedent-setting, or has significant interagency interest.

The EPA Peer Review Handbook, first released in 1998 and last updated in

2015, has also been instrumental in providing guidance on the methods for conducting peer review at the Agency for the past two decades. According to the Handbook the peer review approach can consist of internal or external reviewers and can range from a letter review, an *ad hoc* expert panel review, review of a journal manuscript by a referred scientific journal, review by an established Federal Advisory Committee (FAC), review by an Agency-appointed special board or commission, or review by the National Academy of Science. Given that this guidance reflects long-standing and well-accepted EPA practices on peer review, and given the public's familiarity with it, the Agency is proposing to continue to rely on that established guidance, rather than attempt to modify it or create some new methodology in this rulemaking. As discussed earlier in this proposal, EPA will identify aspects of the analysis on which peer review will be conducted, and the planned methodologies, as part of the draft scoping document that will undergo public comment for each chemical substance that undergoes risk evaluation. These may include novel models or analyses that warrant an in-depth peer review. In addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment will also undergo peer review, as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization which will form the basis of an unreasonable risk determination.

The peer review will address aspects of the science underlying the assessment, including, but not limited to hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. Please note, however, EPA will not seek review of any determination as to whether the risks are ''unreasonable'', which is an Agency policy judgement. The purpose of peer review is for independent review of the science underlying the risk assessment, not to evaluate EPA's policy judgments. TSCA expressly reserves to the Agency the final determination of whether risk posed by a chemical substance is ''unreasonable.'' 15 U.S.C 2605(i). EPA nevertheless will include its unreasonable risk judgment as part of the risk evaluation that is subject to public review and comment.

6. Unreasonable risk determination. The final step of a risk evaluation is for the EPA to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment. The EPA may find that the substance does not present an unreasonable risk of injury to health or the environment under the conditions of use. This will be issued by order, published in the **Federal Register**, and considered to be a final EPA action. Alternatively, the EPA may determine that the substance does present an unreasonable risk under one or more conditions of use, in which case EPA must, pursuant to TSCA section 6(a) (15 U.S.C. 2605(a)), impose requirements to the extent necessary so that the substance no longer presents such risk.

EPA will announce in the **Federal Register** the availability of and solicit public comment on the draft risk evaluation, including the unreasonable risk determination. All comments that could be raised on components of the draft risk evaluation must be presented during this comment period. Any issues not raised during this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

7. Additional publically available information. Pursuant to TSCA section 26(j), EPA will make available: (1) All notices, determinations, findings, consent agreements, and orders; (2) any information required to be provided by the EPA under 15 U.S.C. 2603; (3) a nontechnical summary of the risk evaluation; (4) a list of the studies with the results of the studies, considered in carrying out each risk evaluation; and (5) the final peer review report, including the response to peer review comments.

8. Reassessment of unreasonable risk determination. EPA may reassess a final unreasonable risk determination of a chemical substance at any time based on information available to the Agency.

IV. Request for Comments

While EPA is seeking public comment on all aspects of this proposed rule, there are areas where the Agency specifically requesting public input.

1. Redefining scientific terms. EPA received a number of stakeholder comments regarding EPA's approach to defining a number of important terms within this rule. These terms include ''best available science'', ''weight-of-the-evidence'', ''sufficiency of information'', ''unreasonable risk'', and ''reasonably available information'' among others. Many of the terms used in the proposed rule are not novel concepts and are already in use and the meaning of which is discussed extensively in existing Agency guidance. For example, extensive descriptions for the phrases ''best available science'', ''weight-of-the-evidence'', and ''sufficiency of information'' can be found in EPA's Risk Characterization Handbook (Ref. 24), and in other existing Agency guidance.

EPA believes further defining these and other terms in the proposed rule is unnecessary and ultimately problematic. These terms have and will continue to evolve with changing scientific methods and innovation. Codifying specific definitions for these phrases in this rule may inhibit the flexibility of the Agency to quickly adapt and implement changing science. The Agency intends to use existing guidance definitions and will update definitions and guidance as necessary.

However, the Agency welcomes public comments regarding the pros and cons of codifying these or other definitions and/or approaches for these or any other terms. EPA encourages commenters to suggest alternative definitions the Agency should consider for codification in this procedural rule. Please explain your views as clearly as possible, providing specific examples to illustrate your concerns and suggest alternate wording, where applicable. EPA is specifically requesting comments on whether EPA should define unreasonable risk in the final rule. If so, acknowledging that the statute precludes consideration of costs and other non-risk factors at this step, what factors should EPA consider in making such a determination.

2. Margin of exposure. EPA currently uses a margin-of-exposure (MOE) approach in risk characterization of TSCA risk assessments. Please comment on the strengths and weaknesses of the MOE approach. Are there other approaches (*e.g.* use of hazard indices, use of probabilistic risk assessment) that might better suit the TSCA Risk Evaluation Program? Are there other approaches that provide quantifiable non-cancer risks?

3. Systematic Review. While EPA has included a systematic review approach in the past, and intends to continue to do so, please comment on the need for regulatory text prescribing a specific systematic review approach for hazard identification, including the appropriateness of elements that might be included or concerns about codifying an approach.

4. *Manufacturer Requests.* EPA anticipates that some chemical substances prioritized for risk evaluation have been manufactured by persons who possess unpublished information that could impact the chemical's risk determination. For chemical substances prioritized for risk evaluation, the Agency generally expects to exercise, as needed, among

other authorities, its information-gathering authority pursuant to 15 U.S.C. 2607(a) and 2607(d), likely very early in the process. EPA is specifically requesting comment on approaches to utilizing its information gathering authorities to assure that EPA has the most complete information to make its risk determination. For example, one option might be to incorporate its 15 U.S.C. 2607(a) and 2607(d) authority into the ''Information and information sources'' section of this rule to allow EPA to require, by notice in the **Federal Register**, manufacturers with information subject to 15 U.S.C. 2607(a)(2) and 2607(d) to submit that information to EPA for use in a risk evaluation. EPA is requesting comment on this option and on any more effective alternative methods to exercise this authority within the rule to assure the completeness of the information relevant to the risk evaluation.

The Agency also anticipates the possibility that one manufacturer requests a risk evaluation but other manufacturers of the same chemical who have not joined in the request also possess relevant unpublished information. For manufacturer requests for risk evaluation, the burden is on the requester to include or reference all information that is necessary for EPA to conduct a risk evaluation. Although EPA could use its data collection authority to access information, including unpublished studies, held by entities other than the requestor, the Agency intends to deny requests for risk evaluation if the requester does not have access to the information necessary for risk evaluation.

5. *Peer Review.* As discussed in both the OMB Bulletin and the EPA Peer Review Handbook, there are specific exemption criteria for information that does not necessitate peer review, even if it might be considered to be influential or highly influential. A number of specific circumstances where peer review is not necessary are discussed in section 3.3 of the EPA Peer Review Handbook. Examples of these circumstances include information involving a health or safety issue where the Agency determines that the dissemination is time-sensitive or if an application of an adequately peer-reviewed work product does not depart significantly from its scientific or technical approach. In addition, EPA expects that there will be individual circumstances where a chemical substance is found to not present an unreasonable risk or that findings are similar or the same as other jurisdictions (states or countries) that have reached similar conclusions based on the same information, such that the Agency could determine that peer review is not necessary for that chemical risk evaluation.

EPA expects that many of the risk evaluations conducted under TSCA will necessitate peer review. In cases in which a chemical substance is determined to present an unreasonable risk, the Agency must promptly move to manage the risk, a circumstance that would typically qualify the assessment as ''influential scientific information'' under current guidance and practice. The Agency also expects that some risk evaluations would also be highly influential scientific assessments, *e.g.,* contain novel, controversial, or precedent-setting science with significant interagency interest. EPA also expects that peer review will be warranted in many cases where the Agency determines a chemical substance does not present an unreasonable risk. Aspects of the evaluation may qualify as influential scientific information or highly influential scientific assessment, and thus warrant peer review. Other circumstances where the Agency may determine that peer review is warranted could include circumstances where there are existing private sector standards suggesting concern for a given chemical substance, where existing state assessments differ from the EPA evaluation, or where the public has expressed general concern about the chemical substances effects.

As required under the amended TSCA, chemical substances must be prioritized as either low or high. Those categorized as high are subject to a risk evaluation, and those determined to be low are not. The bar for prioritizing a chemical as a low priority as required under the amended TSCA is fairly high. As such, EPA expects that, as an increasing number of chemical risk evaluations are completed, those chemical substances that present risk to human health or the environment will be managed accordingly, leaving an increasing number of chemicals that do not present an unreasonable risk. The Agency questions whether all future risk evaluations warrant peer review.

EPA is specifically requesting public comment on whether there are circumstances where conducting peer review may not be warranted. What circumstances might qualify, and whether the regulatory text should be adjusted to require EPA to make a case by case determination of whether and to what extent, consistent with the EPA Peer Review Handbook, peer review is warranted for the chemical substance undergoing a risk evaluation. In all cases, the rule would require that this determination, and any peer review activities that are conducted, be documented for each chemical evaluation, starting with the scope document.

6. Reliance on existing guidance and procedures for conducting risk evaluations. As discussed in Unit III.G.1., EPA intends to take advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program. Since each risk evaluation is based on the specific circumstances surrounding the chemical being assessed, EPA has not attempted to codify any specific guidance, method or model. EPA believes that this is necessary to ensure that there is flexibility to address potentially unique circumstances on a chemical basis. EPA is interested in your comments about this approach, and where there is any existing guidance that may be of particular interest for consideration in conducting these risk evaluations. Additionally, EPA asks if the current guidance documents are sufficient and whether there are additional guidance documents that should be relevant but may not be on the lists available on EPA's Web site (*https://www.epa.gov/risk/risk-assessment-guidelines*). Finally, should EPA consider requiring that a list of appropriate guidance documents be included on a case-by-case basis as part of the scoping document that undergoes public review and comment.

7. Interagency collaboration. As discussed in Unit III.B., EPA is committed to ensuring there is interagency engagement and dialogue throughout its risk evaluation process, and has chosen not the limit the potential interagency collaboration by proposing to codify any particular process. EPA is concerned that imposing a single, pre-determined consultation step might lead to an overly bureaucratic process that could limit or complicate ongoing collaboration efforts, and so is not proposing to codify any particular process in this regulation. However, EPA is requesting specific public comment on whether codifying this collaboration at a specific point in the regulation is necessary.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included

in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. USEPA. Information Collection Request (ICR) for the Proposed Rule: Procedures for Chemical Risk Evaluation Under TSCA. EPA ICR No.: 2559.01 and OMB No. 2070—[NEW].
2. EPA. TSCA Work Plan Chemical Assessments: 2014 Update-Final. Office of Pollution Prevention and Toxics. October 2014. *https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf*.
3. National Research Council. Science and Decisions: Advancing Risk Assessment. The National Academies Press. Washington, DC 2009. *http://www.nap.edu/catalog.php?record_id=12209*.
4. EPA. Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum, Washington, DC. EPA/630/P–03/001F. Washington, DC 2005. *https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf*.
5. EPA. Guidelines for Carcinogen Risk Assessment, Review Draft, CEA–F–0644, Office of Research and Development. Washington, DC 1999. *http://cfpub.epa.gov/ncea/raf/cancer.cfm*.
6. EDSTAC. Endocrine Disruptor Screening and Testing Advisory Committee, Final Report, Volume I–II. Washington, DC 1998. *http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/finalrpt.htm*.
7. EPA. Endocrine Disruptor Screening Program; Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing, Washington, DC 2011. *https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0877-0021*.
8. EPA. Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum. Washington, DC March 2007.
9. National Research Council. Risk Assessment in the Federal Government: Managing the Process. The National Academies Press. Washington, DC 1983. *http://www.nap.edu/openbook.php?isbn=0309033497*.
10. National Research Council. Science and Judgment in Risk Assessment. The National Academies Press. Washington, DC 1994. *http://www.nap.edu/catalog.php?record_id=2125*.
11. National Research Council. Understanding Risk: Informing Decisions in a Democratic Society. The National Academies Press. Washington, DC 1996. *http://www.nap.edu/openbook.php?isbn=030905396X*.
12. National Research Council. Toxicity Testing in the 21st Century: A Vision and a Strategy. The National Academies Press. Washington, DC 2007. *http://www.nap.edu/catalog.php?record_id=11970*.
13. National Research Council. Phthalates and Cumulative Risk Assessment: The Tasks Ahead. National Academy Press. Washington, DC 2008. *http://www.nap.edu/catalog.php?record_id=12528*.
14. USEPA. Policy on Evaluating Health Risks to Children. 1995. *https://www.epa.gov/sites/production/files/2014-05/documents/1995_childrens_health_policy_statement.pdf*.
15. USEPA. Guidelines for Developmental Toxicity Risk Assessment. EPA/600/FR–91/001. Risk Assessment Forum. Washington, DC 1991. *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=23162*.
16. USEPA. Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children. Office of Policy, Economics and Innovation. Washington, DC 2006. *http://yosemite.epa.gov/ochp/ochpweb.nsf/content/ADPguide.htm/$File/EPA_ADP_Guide_508.pdf*.
17. USEPA. Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants. Final. EPA/630/P–03/003F. Risk Assessment Forum. Washington, DC 2005. *http://www.epa.gov/raf/publications/guidance-on-selecting-age-groups.htm*.
18. USEPA. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. EPA/630/R–03/003F. Risk Assessment Forum. Washington, DC 2005. *http://www.epa.gov/ttn/atw/childrens_supplement_final.pdf*.
19. USEPA. A Framework for Assessing Health Risk of Environmental Exposures to Children. Final. EPA/600/R–05/093F. Office of Research and Development, National Center for Environmental Assessment. Washington, DC 2006. *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363*.
20. USEPA. Exposure Factors Handbook. EPA/600/R–090/052F. Office of Research and Development, National Center for Environmental Assessment. Washington, DC 2011. *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252*.
21. USEPA. Framework for Human Health Risk Assessment to Inform Decision Making. EPA/100/R–14/001. Office of the Science Advisor, Risk Assessment Forum. 2014. *https://archive.epa.gov/raf/web/pdf/hhra-framework-final-2014.pdf*.
22. Office of Management and Budget Final Information Quality Bulletin for Peer Review.
23. USEPA. Peer Review Handbook. 3rd ed. EPA/100/B–06/002. Science Policy Council. Washington, DC 2006. *https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015*.
24. Risk Characterization Handbook. Science Policy Council Handbook: Risk Characterization, EPA 100–B–00–002, Washington, DC December 2000. *https://www.epa.gov/risk/risk-characterization-handbook*.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket.

B. Paperwork Reduction Act (PRA)

The information collection activities associated with this proposed rule have been submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq.* Specifically, EPA has prepared an ICR to estimate the potential burden and costs associated with the proposed requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. The ICR, which is available in the docket, has been assigned the EPA ICR number 2559.01. You can find a copy of the ICR in the docket for this proposed rule (Ref. 1), and it is briefly summarized here.

Respondents/affected entities: Manufacturers (including importers).

Respondent's obligation to respond: Optional, *i.e.,* needed only if they are requesting an EPA-conducted risk evaluation for a particular chemical substance.

Estimated number of respondents: 10.

Frequency of response: On occasion.

Total estimated annual burden: 960.3 hours. Burden is defined in 5 CFR 1320.3(b).

Total estimated annual cost: $69,353 for burden hours. There are no M&O costs.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of

Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 calendar days after receipt, OMB must receive comments no later than February 21, 2017. Any ICR-related comments will be addressed with the final rule.

C. Regulatory Flexibility Act (RFA)

EPA certifies under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* that this action will not have a significant economic impact on a substantial number of small entities. Although this proposed rule primarily addresses internal EPA procedures and activities associated with conducting risk evaluations for chemical substances as required by TSCA, EPA is also proposing the process and content requirements for a manufacturer (including importer) to request that EPA conduct a risk evaluation on a particular chemical substance. EPA has determined that the process and content requirements proposed will have minimal impact on an entity, regardless of size, because there is no mandate for them to make such a request, and the information they must provide should they decide to make such a request, which involves basic information about the chemical substance and the manufacturer's reasons for requesting the EPA-conducted risk evaluation on that chemical substance, should be readily available to the manufacturer. Estimated potential burden and costs are presented in the ICR (Ref. 1).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not establish an environmental health or safety standard, and is therefore not is not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This is procedural rule that will not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 702

Environmental protection, Chemicals, Chemical Substance, Hazardous substances, Health and safety, Risk Evaluation.

Dated: January 12, 2017,

Gina McCarthy,

Administrator.

Therefore, it is proposed that 40 CFR chapter I, subchapter R, be amended as follows:

PART 702—GENERAL PRACTICES AND PROCEDURES

■ 1. The authority citation for part 702 is revised to read as follows:

Authority: 15 U.S.C. 2605 and 2619.

■ 2. Add subpart B to part 702 to read as follows:

Subpart B—Procedures for Chemical Substance Risk Evaluations

Sec.

§ 702.31 General provisions.

(a) *Purpose.* This subpart establishes the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B) (15 U.S.C. 2605(b)(4)(B)).

(b) *Scope.* These regulations establish the general procedures, key definitions, and timelines EPA will use in a risk evaluation conducted pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(c) *Applicability.* The requirements of this part apply to all chemical substance risk evaluations initiated pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(d) *Enforcement.* Submission to EPA of inaccurate, incomplete, or misleading information by a manufacturer pursuant to a risk evaluation conducted pursuant to 15 U.S.C. 2605(b)(4)(B) is a prohibited act under 15 U.S.C. 2614, subject to penalties under 15 U.S.C. 2615 and Title 18 of the U.S. Code.

§ 702.33 Definitions.

All definitions in TSCA apply to this subpart. In addition the following definitions apply:

Act means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*).

Aggregate exposure means the combined exposures to an individual

from a single chemical substance across multiple routes and across multiple pathways.

EPA means the U.S. Environmental Protection Agency.

Pathways means the mode through which one is exposed to a chemical substance, including but not limited to: Food, water, soil, and air.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Agency who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, including but not limited to, infants, children, pregnant women, workers, or the elderly. EPA may identify a susceptible subpopulation in an individual risk evaluation upon consideration of various intrinsic (*e.g.,* life stage, reproductive status, age, gender, genetic traits) or acquired (*e.g.,* pre-existing disease, geography, workplace) characteristics that may affect exposure or modify the risk of illness or disease.

Reasonably available information means existing information that EPA possesses or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation.

Routes means the particular manner which a chemical substance may contact the body, including absorption via ingestion, inhalation, or dermally (integument).

Sentinel exposure means the exposure(s) of greatest significance, which may be the plausible maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof).

Uncertainty means the imperfect knowledge or lack of precise knowledge either for specific values of interest or in the description of a system.

Variability means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population.

§ 702.35 Chemical substances designated for risk evaluation.

(a) *Chemical Substances Undergoing Risk Evaluation.* A risk evaluation for a chemical substance designated by the Agency as a High-Priority Substance pursuant to the prioritization process described in subpart A, identified under 15 U.S.C. 2605(b)(2)(A), or initiated at the request of a manufacturer or manufacturers under 40 CFR 702.37, will be conducted in accordance with this part, except that risk evaluations that are initiated prior to the effective date of this rule will be conducted in accordance with this part to the maximum extent practicable.

(b) *Percentage Requirements.* The Agency will ensure that, of the number of chemical substances that undergo risk evaluation under 15 U.S.C. 2605(b)(4)(C)(i), the number of chemical substances undergoing risk evaluation under 15 U.S.C. 2605(b)(4)(C)(ii) is not less than 25%, if sufficient requests that comply with 40 CFR 702.37 are made by manufacturers, and not more than 50%.

(c) *Manufacturer Requests for Work Plan Chemical Substances.* Manufacturer requests for risk evaluations, described in 40 CFR 702.35(a), for chemical substances that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or its relevant and applicable successor document will be granted at the discretion of the Agency. Such evaluations are not subject to the percentage requirements in 40 CFR 702.35(b).

§ 702.37 Submission of manufacturer requests for risk evaluations.

(a) *General Provision.* Any request for EPA to conduct a risk evaluation on a chemical substance pursuant to this part must comply with all the procedures and criteria in this section to be eligible to be granted by EPA. A request will meet EPA's criteria if the request includes or references all the information that is necessary for EPA to conduct a risk evaluation addressing all the circumstances that constitute conditions of use of the chemical substance within the meaning of TSCA section 3 (*i.e.,* all circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of).

(b) *Method for Submission.* One or more manufacturers of a chemical substance can request that EPA conduct a risk evaluation on the chemical substance by providing all the following information:

(1) Name, mailing address, and contact information of the entity (or entities) submitting the request. If more than one manufacturer submits the request, all individual manufacturers must provide their contact information.

(2) Full information on the chemical identity of the chemical substance that is the subject of the request. At a minimum, this includes, all known names of the chemical substance, including common or trades names, chemical identity, CAS number, and molecular structure of the chemical substance.

(3) A complete list of the reasonably available information that is consistent with the standards in TSCA section 26(h) and that is relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing all the circumstances that constitute conditions of use of the chemical substance within the meaning of TSCA section 3 (*i.e.,* all circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of). The request need not include copies of the information; citations are sufficient. The request must include or reference all reasonably available information on the health and environment hazard(s) of the chemical substance, health and environmental exposure(s), and exposed population(s). At a minimum this must include information relevant to the following:

(i) The chemical substance's hazard and exposure potential;

(ii) The chemical substance's persistence and bioaccumulation;

(iii) Potentially exposed or susceptible subpopulations they believe to be relevant and that EPA should evaluate in the risk evaluation;

(iv) Whether there is any storage of the chemical substance near significant sources of drinking water;

(v) The chemical substance's conditions of use or significant changes in conditions of use;

(vi) The chemical substance's production volume or significant changes in production volume; and

(vii) Any other information relevant to the risks potentially presented by the chemical substance.

(4) The request must include a commitment to provide to EPA any referenced information upon request. In addition, if the manufacturer previously conducted its own risk assessment of the chemical substance, or possesses or can reasonably obtain any other pre-existing risk assessment, the request must include a commitment to provide such assessments to EPA upon request.

(5) A signed certification that all information contained in the request is accurate and complete, as follows:

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of

my knowledge is, true, accurate, and complete and I have not withheld any relevant information. I am aware there are significant penalties for submitting incomplete, false and/or misleading information, including the possibility of fine and imprisonment for knowing violations.

(c) *Optional Elements.* A manufacturer may provide evidence to demonstrate that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and that as a consequence the request is entitled to preference pursuant to 15 U.S.C. 2605(b)(4)(E)(iii).

(d) *Confidential Business Information.* (1) Persons submitting a request under this subpart are subject to EPA confidentiality regulations at 40 CFR part 2, subpart B.

(2) In submitting a claim of confidentiality, a person must certify the truth of the following statements concerning all information claimed as confidential:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(3) Each claim of confidentiality, other than a claim pertaining to information described in TSCA section 14(c)(2), must be accompanied by a substantiation in accordance with 40 CFR 2.204(e)(4).

(4) Manufacturers must supply a structurally descriptive generic name where specific chemical identity is claimed as CBI.

(5) Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

(e) *EPA Process for Evaluating Manufacturer Requests.* (1) *Review for completeness.* Upon receipt of the request, EPA will verify that the request is facially valid, *i.e.,* that information has been submitted that is consistent with the requirements in 40 CFR 702.37(b) through (d). EPA will inform the submitting manufacturer(s) if EPA has determined that the request is incomplete and cannot be processed. Complete requests will be processed as described in this subpart.

(2) *Public notice and comment.* Within 30 business days of receiving a request that EPA has determined to be valid under paragraph (e)(1) of this section, EPA will submit for publication the receipt of the request in the **Federal Register**, open a docket for that request and provide no less than a 30 calendar day public comment period, during which time the public may submit comments and information relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. In particular, comments identifying any information gaps in the request (*e.g.,* any conditions of use not identified in the request).

(3) *Supplementation of original request.* (i) At any time prior to the end of the comment period, manufacturer(s) may supplement the original request with any new information it receives/obtains.

(ii) At any point prior to the completion of a risk evaluation conducted on a chemical substance at the request of a manufacturer(s), manufacturer(s) are required to supplement the original request upon receipt of information that meets the criteria in 15 U.S.C. 2607(e) and 40 CFR 702.37, or other information that has the potential to change EPA's evaluation of the risk of the chemical substance. Such information must be submitted within 30 calendar days of discovery.

(4) *EPA determination.* Within 9 months of the end of the comment period provided in paragraph (e)(2) of this section, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the criteria and requirements of 40 CFR 702.37. EPA will notify the submitting manufacturer(s) of its determination.

(i) *Request is lacking required information.* (A) The manufacturer(s) have 60 calendar days from receipt of EPA's determination to submit any additional information identified as lacking in the notification.

(B) Failure to submit the additional information will be considered to be a withdrawal of the request to initiate a risk evaluation on the named chemical substance.

(C) Notwithstanding any such withdrawal, manufacturer(s) may submit a subsequent request on the same chemical substance.

(ii) *Compliant request.* EPA will initiate a risk evaluation for all requests for non-TSCA Work Plan Chemicals that meet the criteria in this subpart, until EPA determines that the number of manufacturer-requested chemical substances undergoing risk evaluation is equal to 25% of the High-Priority Substances identified in subpart A as undergoing risk evaluation. Once that level has been reached, EPA will initiate one new manufacturer-requested risk evaluation for each manufacturer-requested risk evaluation completed, as needed to ensure that the number of manufacturer-requested risk evaluations is equal to at least 25% of the High-Priority substances risk evaluation.

(5) *Preferences.* In conformance with 40 CFR 702.35(c), in evaluating requests for TSCA Work Plan Chemicals and requests for non-TSCA Work Plan chemicals in excess of the 25% threshold in paragraph (e)(4)(ii) of this section, EPA will give preference to requests for risk evaluations on chemical substances:

(i) That demonstrate that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce, health or the environment.

(ii) EPA will also give preference to requests where EPA has determined there are relatively high estimates of hazard and/or exposure for the chemical substance.

(iii) Any other factor EPA determines to be relevant.

(6) *Conditions of use considered.* EPA will conduct the risk evaluation on all of the conditions of use of a chemical substance undergoing risk evaluation at the request of a manufacturer, as determined through the scoping process outlined in 40 CFR 702.39(c).

(7) *No preferential treatment.* EPA will not expedite or otherwise provide special treatment to a risk evaluation conducted as a result of a manufacturer request.

(f) *Fees.* Manufacturers must pay fees to support risk evaluations under 15 U.S.C. 2605(b)(4)(C)(ii).

§ 702.39 Evaluation Requirements and Peer Review Procedures.

(a) *Considerations.* (1) Each risk evaluation will include the following components: a Scope, including a Conceptual Model and an Analysis Plan; a Hazard Assessment; an Exposure Assessment; a Risk Characterization; and a Risk Determination.

(2) Existing EPA guidance, where available and relevant, will be used in conducting the risk evaluation. In addition, other scientifically relevant methods or guidance may be used in a risk evaluation.

(3) Where appropriate, a risk evaluation may be conducted on a category of chemical substances. EPA will determine whether to conduct an evaluation on a category of chemical substances, and the composition of the category based on the considerations listed in 15 U.S.C. 2625(c). In addition to the factors specifically enumerated in that provision, EPA may consider the hazards and exposures associated with the category of chemical substances, and the populations likely to be exposed.

(4) EPA will ensure that all supporting analyses and components of the risk evaluation are suitable for their intended purpose, and well-tailored to the problems and decision at hand, in order to inform the development of a technically sound determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment, based on the weight of the scientific evidence.

(5) The extent to which EPA will refine its evaluations for particular conditions of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. To the extent a determination as to the level of risk presented by a condition of use can be made, for example, by the use of accepted science policies (*e.g.,* defaults assumptions or uncertainty factors), and models or screening methodologies, EPA may determine that no further information or analysis is needed to complete its risk evaluation of the use(s).

(6) EPA may conduct a risk evaluation on a chemical substance in phases to allow the Agency to proceed with risk management on particular conditions of use. For example, EPA may determine that a chemical substance presents an unreasonable risk of injury to health or the environment under one or more conditions of use, and address such unreasonable risk through rulemaking under TSCA section 6(a), while other conditions of use remain under evaluation. In all cases in which EPA conducts its risk evaluations in phases, EPA will nevertheless complete a full risk evaluation of the chemical substance for all of the conditions of use identified through the scoping process in 40 CFR 702.39(c) within the time frame in 40 CFR 702.43(d).

(7) In evaluating chemical substances that are metals or metal compounds, EPA will use the *Framework for Metals Assessment of the Office of the Science Advisor, Risk Assessment Forum* dated March 2007, or a successor document that addresses metal risk assessment and is peer reviewed by the Science Advisory Board.

(b) *Information and information sources.* (1) EPA will base each risk evaluation on reasonably available information.

(2) EPA generally expects to initiate a risk evaluation for a chemical substance only when EPA believes that all or most of the information necessary to perform the risk evaluation already exists and is reasonably available. EPA expects to use its authorities under the Act, and other information gathering authorities, when necessary to generate the information needed to perform a risk evaluation for a chemical substance before initiating the risk evaluation for such substance. EPA will use such authorities on a case-by-case basis during the performance of a risk evaluation to obtain or generate information as needed to ensure that EPA has adequate, reasonably available information to perform the evaluation.

(3) Among other sources of information, the Agency will consider information and advice provided by the Science Advisory Committee on Chemicals established pursuant to 15 U.S.C. 2625.

(4) In conducting risk evaluations, EPA will rely on an appropriate combination of information, accepted science policies (*e.g.,* defaults and uncertainty factors), models and screening methodologies. The balance of information, accepted science policies models, and screening methodologies used in risk evaluation will be informed by the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluations. It will also be informed by consideration of the extent to which additional information would reduce the uncertainty in determining whether a chemical substance presents an unreasonable risk of injury to health or the environment.

(5) Where appropriate, to the extent practicable, and scientifically justified, EPA will use information generated without the use of testing on vertebrates in performing risk evaluation.

(c) *Scope of the risk evaluation.* EPA will determine the scope of the risk evaluation to be conducted for each chemical substance based on all of the following:

(1) EPA will identify those uses that constitute the conditions of use that will be assessed during the risk evaluation. Those uses shall be all circumstances under which the Agency determines that the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

(2) When determining the scope, EPA will identify the exposed individuals and populations, including any potentially exposed or susceptible subpopulations as identified by the Agency that EPA plans to evaluate; the ecological characteristics that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.

(3) The combination of reasonably available information, accepted science policies (*e.g.,* defaults and uncertainty factors), models, and screening methodologies that EPA plans to use in the risk evaluation will be documented.

(4) *Conceptual model.* (i) The scope documents will include a Conceptual Model that describes actual or predicted relationships between the chemical substance and human and environmental receptors.

(ii) The Conceptual Model will identify human and ecological health endpoints the EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.

(iii) Conceptual Model development will consider the life cycle of the chemical substance, including manufacture, processing, distribution in commerce, storage, use, and disposal.

(5) *Analysis plan.* (i) The scope documents will include an analysis plan that identifies the approaches, methods, and/or metrics that the EPA plans to use to assess exposures, effects, and risk, including associated uncertainty and variability for each risk evaluation. The analysis plan will also identify the strategy for using information, accepted science policies, models, and screening methodologies.

(ii) Hypotheses about the relationships described in the conceptual model will be described. The relative strengths of (any) competing hypotheses will be evaluated to determine the appropriate risk assessment approaches.

(6) *Developing the Scope.* (i) *Draft scope.* For each risk evaluation to be conducted EPA will publish a document in the **Federal Register** that specifies the draft scope of the risk evaluation the Agency plans to conduct. The document will address the elements in paragraphs (c)(1) through (5) of this section.

(ii) *Timeframes.* EPA generally expects to publish the draft scope no later than 3 months from the initiation of the risk evaluation process for the chemical substance, and to allow a period of 30 calendar days during which interested persons may submit comment on EPA's draft risk evaluation scope. EPA will open a docket to facilitate receipt of public comments.

(iii) *Public comments.* All comments that could be raised on the matters addressed and issues presented in the

published risk evaluation scope document must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

(iv) *Final scope.* (A) The Agency will, no later than 6 months after the initiation of a risk evaluation, publish a document in the **Federal Register** that specifies the final scope of the risk evaluation the Agency plans to conduct. The document shall address the elements in paragraphs (c)(1) through (5) of this section.

(B) For a chemical substance designated as a High-Priority Substance under 40 CFR part 702 subpart A, EPA will not publish the final scope of the risk evaluation until at least 12 months have elapsed from the initiation of the prioritization process for the chemical substance.

(d) *Hazard assessment.* (1) The hazard information relevant to the chemical substance will be evaluated using endpoints identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section, for the identified exposure scenarios, including any identified potentially exposed or susceptible subpopulation(s).

(2) The hazard assessment process will identify the types of hazards to health or the environment posed by the chemical substance. This process includes the identification, evaluation, and synthesis of information to describe the potential health effects of the chemical substance.

(3) Based on the final scope document published pursuant to paragraph (c)(6)(iv) of this section, potential human and environmental hazard endpoints will be evaluated, including, as appropriate; acute, subchronic, and chronic effects during various stages of reproduction or life stage.

(4) The relationship between the dose of the chemical substance and the occurrence of human and environmental health effects or outcomes will be evaluated.

(5) Studies evaluated may include, but would not be limited to: Human epidemiological studies, in vivo and/or in vitro laboratory studies, mechanistic or kinetic studies in a variety of test systems, including but not limited to toxicokinetics and toxicodynamics, computational toxicology, data from structure-activity relationships, high-throughput assays, genomic response assays, and ecological field data.

(6) Hazard identification will include an evaluation of the strengths and limitations of the reasonably available information.

(7) *Human health hazard assessment.* The hazard assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section. Reasonably available information used to characterize risk to susceptible subpopulation(s) may include, but may not be limited to:

(i) Population-based epidemiology studies that identify risk factors and susceptible subpopulations;

(ii) Information related to geographic location of subpopulations;

(iii) Models that represent health effects of relevant subpopulations; and

(iv) Any other relevant, scientifically valid information, methodology, or extrapolation.

(8) *Environmental health hazard assessment.* The relationship between the chemical substance and the occurrence of an ecological hazard elicited will be evaluated using reasonably available information including but not limited to: Field or laboratory measurements, modeling strategies, extrapolations or incident data.

(e) *Exposure assessment.* (1) Where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use will be considered.

(2) For the conditions of use, exposures will be evaluated using reasonably available information.

(3) Chemical-specific factors including, but not limited to: Physical-chemical properties and environmental fate parameters will be examined.

(4) *Human health exposure assessment.* The exposure assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section. Reasonably available information used to characterize exposure to susceptible subpopulation(s) may include:

(i) Population-based epidemiology studies that identify risk factors and susceptible subpopulations;

(ii) Information related to geographic location of subpopulations;

(iii) Models that represent exposure or health effects of relevant subpopulations; and

(iv) Any other relevant, scientifically valid information or methodology.

(5) *Environmental health exposure assessment.* (i) The environmental health exposure assessment will characterize and evaluate the interaction of the chemical substance with the ecological characteristics identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section.

(ii) Exposures considered will include individuals as well as communities, depending on the chemical substance and the ecological characteristic involved.

§ 702.41 Risk characterization and peer review procedures.

(a) *Risk Characterization Considerations.* EPA will: (1) Integrate the hazard and exposure assessments into quantitative and/or qualitative estimates of risk for the identified populations (including any potentially exposed or susceptible subpopulation(s) identified in the final scope document published pursuant to 40 CFR 703.39(c)(6)(iv) and ecological characteristics for the conditions of use; and

(2) Describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for that consideration.

(b) The Risk Characterization will summarize, as applicable, the considerations addressed throughout the evaluation components, in carrying out the obligations under 15 U.S.C. 2625(h). This summary will include, as appropriate, a discussion of:

(1) *Considerations regarding uncertainty and variability.* Information about uncertainty and variability in each step of the risk evaluation (*e.g.,* use of default assumptions, scenarios, choice of models and information used for quantitative analysis) will be integrated into an overall characterization and/or analysis of the impact of the uncertainty and variability on estimated risks. EPA may describe the uncertainty using a qualitative assessment of the overall strength and limitations of the data used in the assessment.

(2) *Considerations of data quality.* A discussion of issues associated with data quality (*e.g.,* reliability, relevance, and whether methods employed to generate the information are reasonable for and consistent with the intended use of the information), as well as assumptions used, will be included to the extent necessary. EPA also expects to include a discussion of the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models used in the risk evaluation.

(3) *Considerations of alternative interpretations.* If appropriate and

relevant, a discussion of alternative interpretations of the data and analyses will be included.

(4) *Considerations for environmental risk evaluations.* For environmental risk evaluations, it may be necessary to discuss the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

(c) *Peer Review.* The *EPA Peer Review Handbook* (2015), the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin), or other available, relevant and applicable methods consistent with 15 U.S.C. 2625, will serve as the guidance for peer review activities. Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A).

§ 702.43 Unreasonable risk determination.

The EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use as identified in the final scope document published pursuant to 40 CFR 702.39(c)(6)(iv).

§ 702.45 Risk evaluation timeframes and actions.

(a) *Draft risk evaluation timeframe.* The EPA will publish a draft risk evaluation in the **Federal Register** and provide no less than a 30-day comment period, during which time the public may submit comment on EPA's draft risk evaluation.

(1) EPA will open a docket to facilitate receipt of public comment.

(2) All comments that could be raised on the matters addressed and issues presented in the draft risk evaluation must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

(b) *Final risk evaluation.* (1) EPA will complete a risk evaluation for the chemical substance as soon as practicable, but not later than 3 years after the date on which the Agency initiates the risk evaluation.

(2) The Agency may extend the deadline for a risk evaluation for not more than 6 months.

(3) EPA will publish the final risk evaluation in the **Federal Register**.

(c) *Final determination of unreasonable risk.* Upon determination by the EPA that a chemical substance does present an unreasonable risk of injury to health or the environment, the Agency will initiate action as required pursuant to 15 U.S.C. 2605(a).

(d) *Final determination of no unreasonable risk.* A determination by the EPA that the chemical substance does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final EPA action, effective on the date of issuance of the order.

(c) *Reassessment.* EPA may reassess an unreasonable risk determination based on a review of available information.

§ 702.47 Publically available information.

For each risk evaluation, EPA will maintain a public docket at *http://www.regulations.gov* to provide public access to the following information, as applicable for that risk evaluation:

(1) The draft scope, final scope, draft risk evaluation, and final risk evaluation;

(2) All notices, determinations, findings, consent agreements, and orders;

(3) Any information required to be provided to the Agency under 15 U.S.C. 2603;

(4) A nontechnical summary of the risk evaluation;

(5) A list of the studies, with the results of the studies, considered in carrying out each risk evaluation;

(6) The final peer review report, including the response to peer review comments; and

(7) Response documents to the public comments on the draft risk evaluation.

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